

The Use of Pharmacoeconomics and Pharmacoepidemiology in Your Local MTF P&T Process

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Presentation Objectives

- Participants will be able to list tips on how to enhance their presentation of health economic and pharmacoepidemiological data to decision makers.
- Participants will be able to describe why decision makers lack faith in health economic studies.
- Participants will be able to describe why decision makers at the “local level” lack trust in decisions made at a “central” or higher level.

- **Participants will be able to define and explain incremental cost-effective analysis.**

Levels of Decision Makers

- **Health care decision making is done at multiple levels within our health care system.**
- **Some are done at the very top or at the “central” level. These are normally policy or program level decisions and include such items as drug pricing, reimbursement for drugs and even formulary drug selection.**

- **Some decisions are made at the local level—the hospital, health plan or practitioner practice level. For example, treatment guidelines and formulary decisions can be at the local level. Please note that in the U.S. most decisions are done at the local level, however with the advent of major health care programs this is changing. More and more decisions are being made at higher levels.**
- **The applications of economic analyses are at the both the “central” and “local” area.**

Good practice elements of economic analyses apply to all levels of decision making, however, there are critical differences between central decisions makers and local level decision makers.

Differences Between Central and Local Level Decision Making

- **Usually at the central level, expertise is available to evaluate the methodological quality of the studies. This may not be the case at some local levels.**
- **At the central level there is normally a standardized or prescribed process for presenting the economic data to decision makers. Normally a set of guidelines need to be followed. (For example, the Academy of Managed Care Format process may be used).**

- **The implications of these differences is that at the local level, there is concern over whether the decisions made at the central level can be trusted and whether there is biases in research sponsored by the drug manufacturer.**
- **Whereas at the central level a company submission is by definition advocacy for their product and thus must be evaluated critically.**

Concerns with Economic Studies

- At all levels, there is a concern for the transparency of studies. This for all economic studies, including results from clinical trials, but applies more to modeling studies where assumptions are extensively used.
- One major concern is: Do the modeling assumptions apply to the local environment? Needless to say, but not all MTFs are the same in regard to patient characteristics.

- **Decision makers prefer observed data over unobserved data—modeling data.**
- **Likewise, expert panel data are considered inferior to actual data from patient charts, clinical studies, or administrative databases.**

Relevance

- The key issue which most pharmacoeconomic studies fail to explore is **BUDGETARY IMPACT!**
- Cost-effectiveness ratios provide a value for the money, however they say nothing about total cost not the impact of the costs.
- Decision makers are concerned with affordability—can I stay within the budget?
- Affordability is about the issue of demand or volume of the drug and whose budget will be impacted.

Decision makers want to see a budgetary perspectives explored and well as budgetary impact.

This may be a challenge for central decision makers due to the diversity of the MTFs. The decision may save funds centrally but adversely affect an MTF.

Also, if savings can be achieved in another budget or in the future, it can present a problem for those with the “silo” budget mentality.

Application to the Local Environment

- **As mentioned, many times local decision makers have doubts as to whether the “central decision” is useful for their location or patient population.**
- **Thus, decision makers need to be prepared to give a presentation incorporating the local characteristics. Many times this is dealt with the use of sensitivity analyses or interactive models.**

To Assist Decision Makers Economic Analyses Need to Report

- 1. Description of the relevant patient population**
 - Needs to include the size of the population which gets at budgetary impact.
 - Need to be careful of off-label uses of the product.
- 2. Budgetary perspective and budget impact**
 - Needs to include all relevant budgets and the impact on each budget. (ie. If the decision affects nursing care than this needs to be included).

3. Cost-consequence analysis

- **This disaggregates the costs and outcomes prior to using any cost-effectiveness or cost-utility ratios.**
- **This would compare the disaggregated costs and outcomes of the new therapy with existing therapies.**

To Assist Decision Makers Economic Analyses Need to Report

- 4. Provide the costs, consequences and cost-effectiveness by patient subgroups.**
 - **When relevant patient population groups exists, decision makers want to know how the value varies by sub-group.**
- 5. Practical implications of adopting the new therapy**
 - **Sometimes decision makers do not understand incremental cost-effectiveness analyses, thus present the results in simple statements of the implications on patients or on the budget.**

To Assist Decision Makers Economic Analyses Need to Report

- 6. Explain all assumptions and data sources.**
- 7. Conduct a sensitivity analyses using decision makers' own data and own assumptions—in other words use the “local” data to determine the impact on outcomes and budgets.**

Incremental Cost-Effectiveness Analysis

- **Incremental Cost-Effectiveness (ICE) analysis is used to compare competing alternatives for the same condition. This includes choices in drug therapy for hypertension, cholesterol reduction or it can be used to compare doses or strengths of the same drug.**

Incremental Cost-Effectiveness Analysis

- **With incremental cost-effectiveness analysis, the normal CE analysis does not apply without some modification, because the alternatives are no longer independent. The benefits of two antihypertensives are not additive.**
- **The paradigm needs to be modified to incorporate mutually exclusive competing choices for the same condition.**

- **First, let's look at the basic CE model. Here's an example taken from the textbook *Valuing Health Care* written by Frank Sloan. The example list cancer screening programs, effectiveness as quality adjusted life years, program costs and the CE ratio.**

You have \$10 million to allocate, what programs would you select?

Program	QALYs	Pgm Costs	C/E ratio \$
A	500	\$1,000,000	\$2,000
B	500	\$2,000,000	\$4,000
C	200	\$1,200,000	\$6,000
D	250	\$2,000,000	\$8,000
E	100	\$1,200,000	\$12,000
F	50	\$800,000	\$16,000
G	100	\$1,800,000	\$18,000
H	100	\$2,200,000	\$22,000
I	150	\$4,500,000	\$30,000

Source: Sloan Frank, *Valuing Health Care*, p180

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- **The optimal allocation of the \$10 million would be to adopt plans A, B, C, D, E, F and G. This is up to the cut-off point of \$18,000 per QALY. Overall, this would provide a total of 1,700 QALYs saved.**
- **What this means is that if a new program were to be added, it must provide a savings of less than \$18,000/QALY.**
- **If your budget is only \$3 million, what is the cut-off point?**

- **In this simple example, CE ratios are used in a well defined budget with a well defined objective. This is not always the case; many times the budget is not explicitly limited. Also, sometimes costs are difficult to calculate (indirect costs, non-medical costs, future health costs with extension of life, etc.) and many assumptions are made in calculating costs.**

Application of Incremental CE to the Example

- **As mentioned incremental cost-effectiveness (ICE) analysis involves the comparisons of competing alternatives.**
- **Consider the very simple hypothetical example of adding a new cancer screening program to the previous example.**

- In this example, the key is that to include this new cancer screening program **it must come out of the original \$10 million budget.** This means the funds must come from program G with the \$18,000/QALY.
- Take a look at the following data on the new screening programs.

Cancer Program	QALYs	Costs (\$)	CE ratio (\$)
J₀ (no program)	0	0	0
J₁	10	\$50,000	\$5,000
J₂	15	\$150,000	\$10,000

- It is tempting to select J_2 because it has a CE ratio of \$10,000 and it is less than the CE ratio \$18,000 from program G. Plus it has 15 QALYs compared to only 10 for J_1 .
- **This is incorrect** — because it avoids the availability of J_1 which gives two-thirds the value compared to J_2 (10 vs. 15 QALYS) and costs two-thirds less.
- What is needed is an incremental CE ratio calculation.

An incremental cost-effectiveness ratio (ICER) is calculated by dividing the incremental or extra cost of the treatment by the incremental or extra effectiveness.

$$\text{Incremental Cost Effectiveness Ratio} = \frac{\text{Extra Cost}}{\text{Extra Effectiveness}}$$

When comparing a more expensive therapy (Treatment B) with a less expensive treatment (Treatment A), ICER is calculated:

$$\text{ICER} = \frac{(\text{Cost}_B - \text{Cost}_A)}{(\text{Effect}_B - \text{Effect}_A)}$$

- **Basically ICER shows the change in cost per change in effect. Effects can be measure in a variety ways such as blood pressure readings, hemoglobin A1Cs, life years or quality adjusted life years, tumor response.**
- **Obviously, the compared treatments must be measured in the same end points.**

Calculation of ICER Comparing J₂ with J₁

$$\frac{\text{Cost } J_2 - \text{Cost } J_1}{\text{Effect } J_2 - \text{Effect } J_1} = \text{ICER}$$

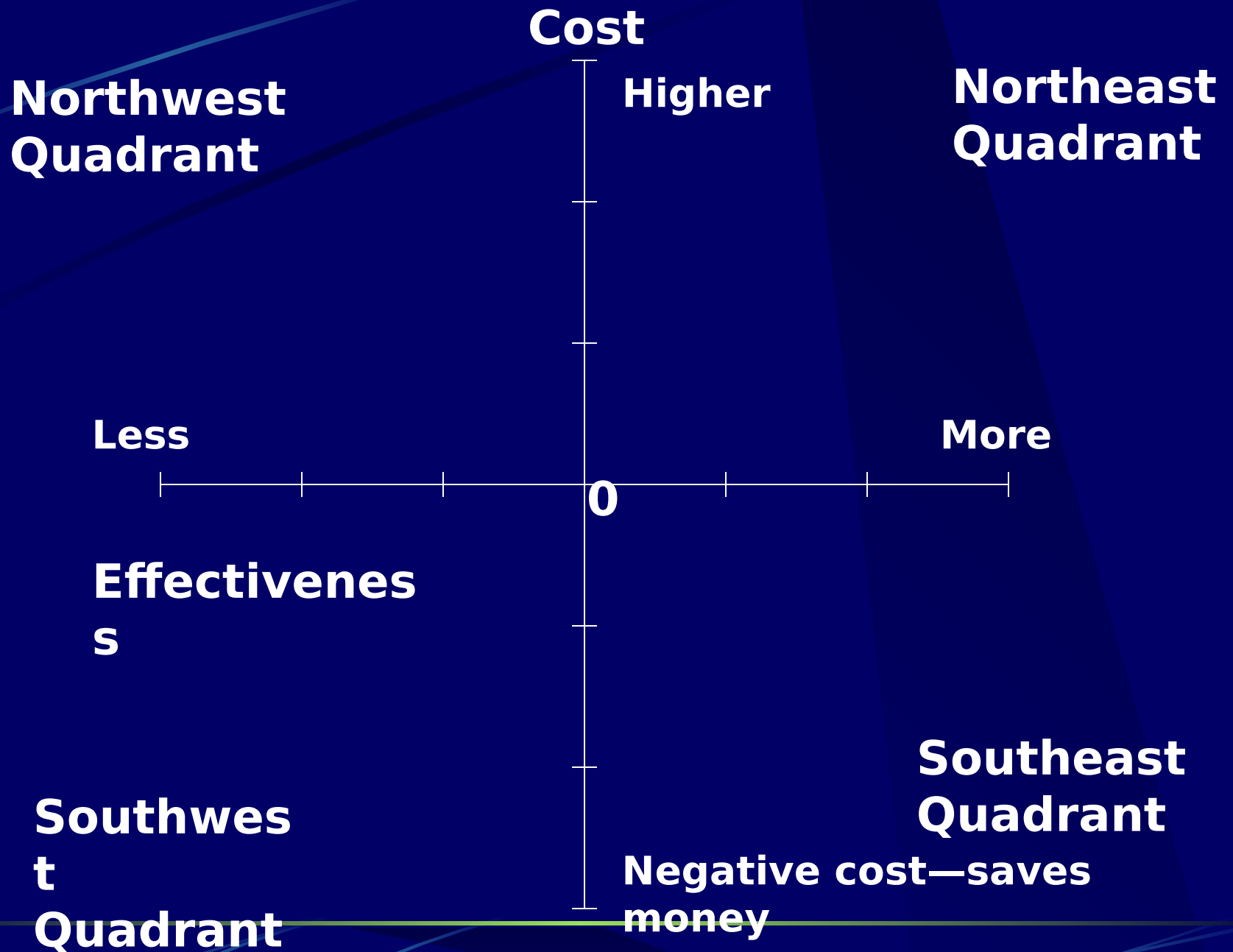
$$\frac{(\$150,000 - \$50,000)}{0.15 - 0.10} = \$20,000/\text{QALY}$$

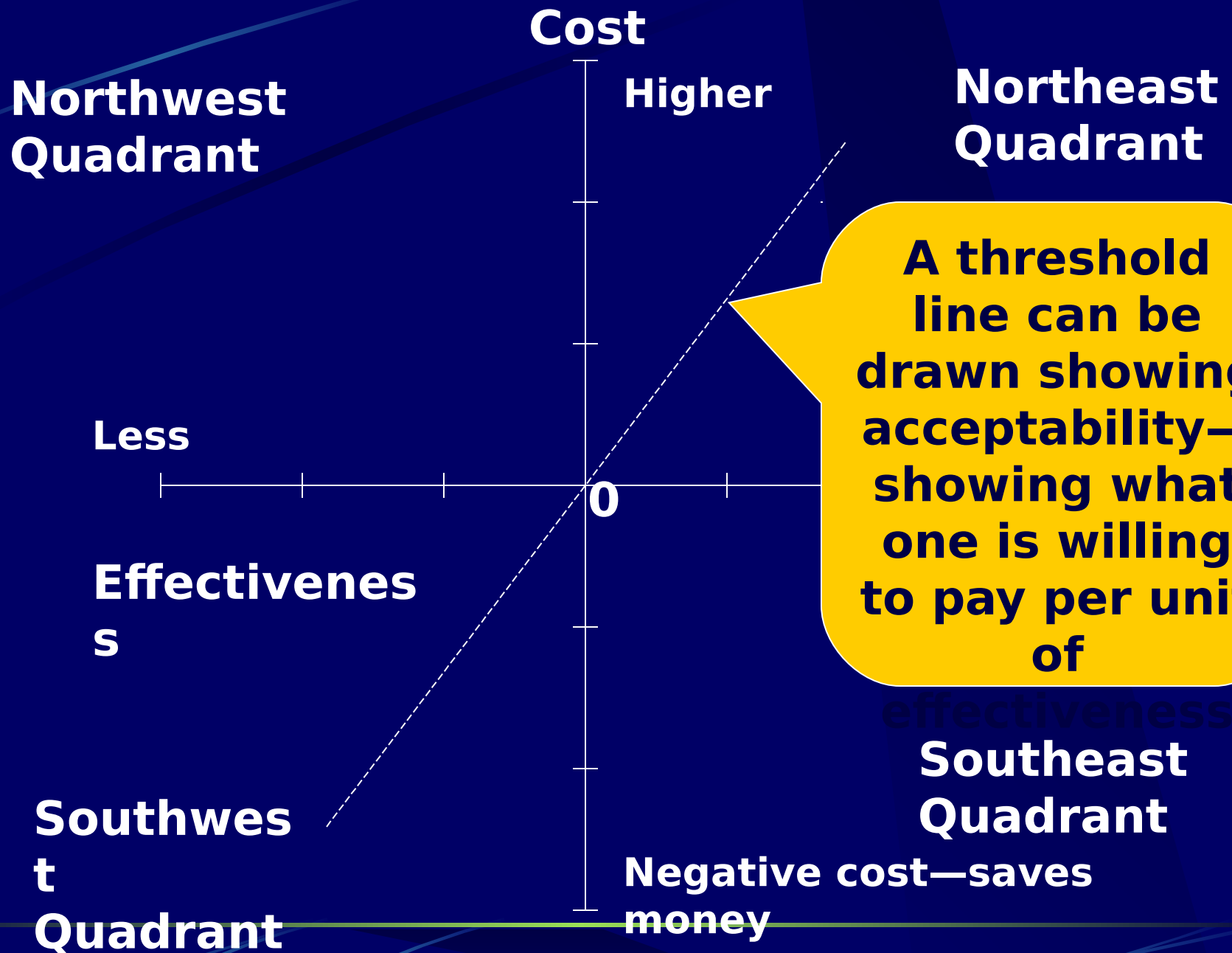
Note: This is much higher than the \$18,000 for program G.

- **Since the incremental CE is \$20,000/QALY which exceeds the critical value of \$18,000 for program G, the optimal allocation would be to fund J_1 . You would need to reduce the allocation to program G by \$50,000 and not fund J_2 .**

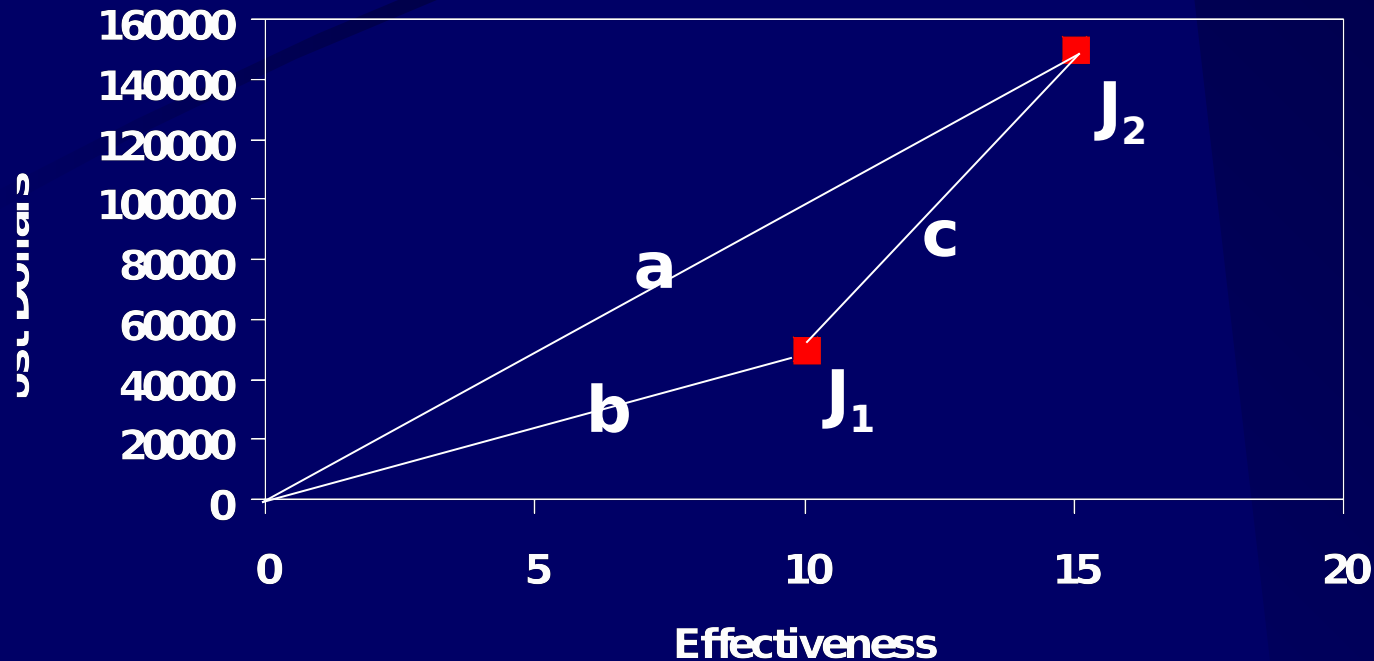
Cost-Effectiveness Planes

- **To help understand CE ratios and to compare CE ratios between alternatives, CE ratios can be expressed graphically using a cost-effectiveness plane.**
- **The next slide illustrates a cost-effectiveness plane.**





Example of Using a Cost-Effectiveness Plane



Example only depicts the Northeast quadrant

Please note that the slopes of lines a and b equal the CE ratios for J_1 and J_2 respectively.

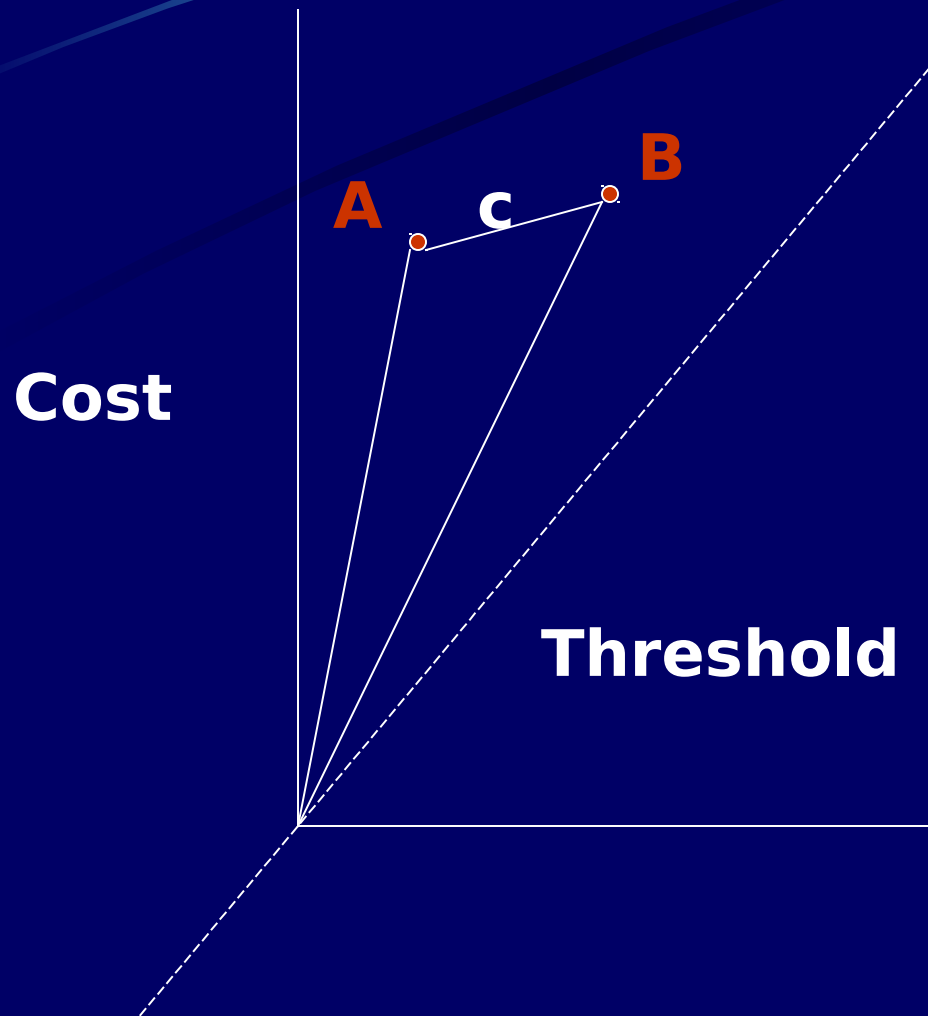
Also, the slope of line c equals the incremental CE ratio

Limitation on ICER

- **First, this is a very simple example showing the basics of incremental CE. Obviously, there may be other issues, especially political issues that may affect the decision. Please note that ICER has been extensively used to evaluate competing drug products. However, in most of these analysis the comparisons are in the Northwest quadrant.**

- **Caution: ICE can be made to look cost-effective if the comparison is made with a sufficiently cost-ineffective alternative therapy.**
- **A rule of thumb is to consider only options whose incremental CE ratios are lower than the most expensive competing option.**
- **Another disadvantage is that CE or ICER only uses one outcome measure. You may have to use other outcomes measures.**

Example of Misleading ICER



The slope of line c (ICER) is smaller than the threshold and one could interpret the results as B being acceptable compared to A.

However, both A and B are quite cost ineffective

- **Lastly, ICER are not clear when cost and effectiveness have opposite signs. The ICER value will be negative and the negative value may not reflect the relative preference of the alternatives.**

Hope the information will be helpful and assist you in examining competing alternatives. As with most cost analyses, they are NO “silver bullets.”

One needs to interpret the results very carefully because the assumptions used and how costs are calculated in mathematical models may not fit all situations.

**Thanks so much. It has been a
pleasure.**

Enjoy the meeting!

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